



**ALKO Diagnostic Corporation**  
*A Life Sciences International Company*

DEC 18 1996

K962864

## **510(k) Summary**

### **tHb Cal Standard**

for Instrumentation Laboratory CO-Oximeters and Oximeters.

The product encompassed by this 510(k) submission is a Class II (81KRZ) In Vitro Diagnostic Solution manufactured by ALKO Diagnostic Corporation, 333 Fiske Street, Holliston, MA 01746. The tHb Cal Standard is intended for use in calibrating the total hemoglobin channel of the IL CO-Oximeters and Oximeters. Instrumentation Laboratory Company is the original equipment manufacturer (OEM) of the analyzer and of predicate Cal Dye™ Reference Standard which is necessary for calibrating the total hemoglobin channel on the IL CO-Oximeters and/Oximeters.

The tHb Cal Standard is intended to serve as direct replacement to like named product manufactured by Instrumentation Laboratory Company. ALKO Product A331-50 (tHb Cal Standard) is equivalent to Instrumentation Laboratory product 33150-50 (Cal Dye™ Reference Standard).

ALKO uses a similar composition, description and packaging design as that used by Instrumentation Laboratory Company in its products. ALKO has shown performance equivalence of its product to Instrumentation Laboratory Company's product in the following manner:

- Through functional tests where results were obtained on Instrumentation Laboratory CO-Oximeters/Oximeters with ALKO product and were compared with results obtained on the same analyzer calibrated with Instrumentation Laboratory product.
- Through a precision study where ALKO product was used on an Instrumentation Laboratory Analyzer and samples were measured over 5 runs.
- Through a comparative analysis where tHb Cal Standard and IL Cal Dye™ Reference Standard were measured and compared with the assayed tHb values.

A summary of the results of these studies follows:

**PERFORMANCE CHARACTERISTICS****1. Precision Data**

Precision data were collected from the analysis of three levels of IL CO-OX controls (Human Hemoglobin based), 3 times per run, one run per day for 5 days, on a 482 analyzer calibrated with ALKO tHb Cal Standard. A separate calibration was performed prior to each run.

**tHb**

Level		N	Mean	STD	CV%	Min	Max
1	Total	15	16.9	0.1181	0.6993	16.8	17.2
	Run to Run	5	16.9	0.0646	0.3826	16.8	17.0
2	Total	15	13.8	0.1147	0.8340	13.6	13.9
	Run to Run	5	13.8	0.0806	0.5857	13.6	13.9
3	Total	15	7.2	0.0772	1.0758	7.1	7.4
	Run to Run	5	7.2	0.0533	0.7435	7.1	7.3

**2. Comparative Data**

Comparative data were collected from the analysis of ALKO and IL tHb Cal Standards measured on IL 282 and 482 Analyzers.

**tHb**

Instrument	Product P/N, Lot No	N	Mean	STD	CV%	tHb min.- max.	Assay Value
on IL 282	IL 33150, lot N0931981	15	14.7	0.0653	0.4450	14.6 - 14.8	14.8
	ALKO A331-50, lot 10624	15	15.0	0.0499	0.3316	15.0 - 15.1	15.0
on IL 482	IL 33150, lot N1257163	15	14.9	0.0730	0.4901	14.8 - 15.0	14.9
	ALKO A331-50, lot 50128	15	14.8	0.0442	0.2993	14.7 - 14.8	14.8

### 3. Functional Tests

Functional tests of ALKO tHb Cal Standard were performed on IL 282 and 482 Analyzers and compared to IL Cal Dye™ Reference Standard. Both analyzers were calibrated with ALKO and IL tHb Standards separately. Three levels of IL CO-OX controls (Human Hemoglobin based) were measured in triplicate. The mean values are shown below.

#### a) IL 282 Analyzer

		tHb(g/dL)	%O2Hb	%COHb	%MetHb	O2 Ct (Vol%)
Calibrated with IL Cal Dye™ Reference Standard	Level 1	17.2	39.3	60.4	0.2	9.4
	Level 2	12.8	96.3	3.7	0.5	17.2
	Level 3	6.4	76.0	24.1	0.2	6.7
Calibrated with ALKO tHb Cal Standard	Level 1	17.4	39.4	60.4	0.3	9.5
	Level 2	13.0	96.1	4.0	0.5	17.4
	Level 3	6.5	75.8	24.3	0.4	6.8
Assayed Control Values	Level 1	16.6-17.6	37.1-41.1	58.6-62.0	-0.9-3.1	8.5-10.5
	Level 2	12.3-13.3	93.5-98.5	1.9-5.3	-1.1-2.9	16.3-18.7
	Level 3	6.0-7.0	73.7-77.7	22.1-25.5	-1.0-3.0	6.2-7.4

#### b) IL 482 analyzer

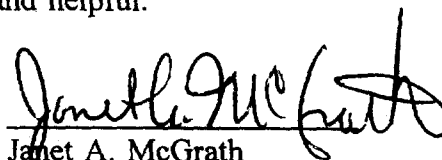
		tHb(g/dL)	%O2Hb	%COHb	%MetHb	O2 Ct (Vol%)	% RHb
Calibrated with IL Cal Dye™ Reference Standard	Level 1	16.8	39.0	60.5	0.1	9.1	0.4
	Level 2	13.7	97.3	2.2	0.2	18.5	0.3
	Level 3	7.1	77.3	22.4	0.2	7.6	0.1
Calibrated with ALKO tHb Cal Standard	Level 1	16.9	39.1	60.1	0.4	9.2	0.4
	Level 2	13.8	97.1	2.1	0.3	18.6	0.4
	Level 3	7.1	77.2	22.4	0.2	7.6	0.3
Assayed control Values	Level 1	16.6 to 17.6	35.6 to 39.6	59.6 to 63.0	-0.8 to 3.2	8.1 to 10.1	-1.3 to 1.1
	Level 2	13.3 to 14.3	93.4 to 98.4	1.5 to 4.9	-0.9 to 3.1	17.4 to 19.8	-1.5 to 0.9
	Level 3	6.7 to 7.7	74.1 to 78.1	21.0 to 24.4	-0.6 to 3.4	7.1 to 8.3	-1.5 to 0.9

Conclusion

ALKO manufactures products that serve as functional equivalents to consumable distributed by Original Equipment Manufacturer. All such products are manufactured with the intent of complying with the Good Manufacturing Practice Regulations.

As previously stated the product encompassed by this request serves as a functional equivalent to the product currently manufactured and marketed by Instrumentation Laboratory of Lexington, MA USA. We believe that Instrumentation Laboratory has received 510 (k) market approval given that they are currently distributing the IL CO-Oximeter/Oximeter instruments and related consumable domestically. The previously described labeling and performance verification should provide adequate documentation as to the equivalence of the ALKO Product.

I hope you find the documentation provided informative and helpful.

  
Janet A. McGrath  
Regulatory Affairs